

REMARKS

The office action dated June 6, 2007 (the "Office Action") has been received and noted. Claims 13-26 were examined. Claims 13-26 were rejected. Claims 17 and 23 are cancelled. Claims 13 and 21 are amended. Support for the amendments can be found in, for example, previously pending claims 17 and 23 and Examples 1-8 of the Application. As such, no new matter has been added. Claims 13-16, 18-22 and 24-26 remain in the Application. Reconsideration of the pending claims is respectfully requested in view of the above amendments and following remarks.

I. Claims Rejected Under 35 U.S.C. § 112

Claims 13-16, 18-22 and 24-26 were rejected under 35 U.S.C. § 112, first paragraph, because, according to the Examiner, the specification, while being enabling for process of increasing the level of interleukin-1 receptors and tumor necrosis factor receptors, does not reasonably provide enablement for all cytokine receptors in the blood. Independent claims 13 and 21 have been amended to recite, "wherein the cytokine receptors are selected from the group consisting of interleukin-1 receptors and tumor necrosis factor receptors." In view of the amendments, Applicants respectfully request withdrawal of the rejection.

II. Claims Rejected Under 35 U.S.C. § 102

Claims 13-14 and 16-24 were rejected under 35 U.S.C. § 102(b) as being anticipated by *Thalidomide for the Treatment of Oral Aphthous Ulcers in Patients with Human Immunodeficiency Virus Infection* by Jacobson et al. ("*Jacobson*"). A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. MPEP § 2131. Applicants respectfully submit that each and every element, either expressly or inherently, in amended claims 13 and 21 and their respective dependent claims is not set forth in the cited references.

Amended independent claim 13 recites:

A process, comprising:

contacting blood or a fraction thereof with a therapeutic substance selected from the group consisting of tetracycline, doxycycline, vibramycine, terramycine and salts thereof thereby increasing the level of cytokine receptors in the blood or the fraction thereof, wherein the cytokine receptors are selected from the group consisting of

interleukin-1 receptors and tumor necrosis factor receptors; and

after the contacting, isolating the blood or the fraction thereof having the increased cytokine receptors thereby producing a composition suitable for administration for the treatment of a disease, condition or disorder.

(App., claim 13.) Amended independent claim 21 recites:

A process, comprising:

contacting blood *in vivo* with a therapeutic substance selected from the group consisting of tetracycline, doxycycline, vibramycine, terramycine and salts thereof thereby increasing the level of cytokine receptors in the blood, wherein the cytokine receptors are selected from the group consisting of interleukin-1 receptors and tumor necrosis factor receptors;

after the contacting, collecting a portion of the blood; and

after the collecting, processing the portion of the blood to isolate a blood fraction comprising cytokine receptors.

(App., claim 21.) Representatively, Examples 1-8 of the Application show the effect of at least one of tetracycline, doxycycline, vibramycine, terramycine or a salt thereof contacted with blood and/or cells (i.e., *in vivo* or *in vitro*) resulting in a increase of interleukin-1 receptors and/or tumor necrosis factor receptors, isolated in a blood fraction, and administered to a mammal to treat a disease. (App., Exs. 1-8.)

By contrast, *Jacobson* is directed to the administration of 200 mg of thalidomide for the treatment of oral aphthous ulcers in HIV-infected patients. (*Jacobson*, Abstract.) *Jacobson* does not disclose “contacting blood or a fraction thereof with a therapeutic substance selected from the group consisting of tetracycline, doxycycline, vibramycine, terramycine and salts thereof thereby increasing the level of cytokine receptors in the blood or the fraction thereof, wherein the cytokine receptors are selected from the group consisting of interleukin-1 receptors and tumor necrosis factor receptors,” as recited in independent claims 13 or 21. (App., claims 13, 21.)

Moreover, *Jacobson* does not disclose “administering the blood or fraction thereof to treat a disease, condition or disorder,” as recited in dependent claims 20 and 26. (App., claims 20, 26.) These claims have not been specifically addressed by the Examiner and Applicants believe these claims to be allowable over the cited reference even without the amendments.

With respect to the Examiner’s remarks on inherency beginning on page 6 of the Office Action, first paragraph, Applicants respond as follows: precedent case law supports that, with respect to process of use claims, new and unobvious uses of old structures and compositions are subject to patentability. MPEP § 2112.02. As a result, the discovery of a new use for an old structure based on unknown properties of the structures can be patentable to the discoverer of the

process of using. *In re Hack*, 245 F.2d 246, 248 (C.C.P.A. 1957.) In the pending Application, at least one new “use” is the “administering the blood or fraction thereof to treat a disease, condition or disorder,” as recited in dependent claims 20 and 26 after following the protocol recited in independent claims 13 and 21 (on which dependent claims 20 and 26 depend, respectively). (App., claims 13, 20-21, 26.) Such use is not described in *Jacobson*. Thus, with respect to the Examiner’s statement that “[t]he burden is shifted to the applicant to show that the prior art product does not inherently possess the same properties as the instantly claimed product, citing *In re Spada* as support for this statement (Office Action, p.6.), Applicants respectfully remind the Examiner that Applicants are not claiming a product, but rather a process. Thus, MPEP section 2112.01 (*In re Spada*) is not applicable, but rather MPEP section 2112.02 (*In re Hack*).

With respect to the Examiner’s remarks regarding the alleged “preamble” beginning on page 6 of the Office Action, Applicants respond as follows: the list of diseases recited in dependent claims 20 and 26 are not “preamble,” and, moreover, are not relied on to distinguish Applicants’ claimed invention. Instead, since the claims are directed to a process, the relevant language is “***administering*** the blood or fraction thereof to treat a disease, condition or disorder,” as recited in dependent claims 20 and 26. This step is not an “intended use” but rather an actual use and thus, entitled, patentable weight. *See* MPEP § 2112.02.

In view of the above amendments and remarks, Applicants respectfully submit that independent claims 13 and 21 and their respective dependent claims are allowable over the cited reference.

III. Claims Rejected Under 35 U.S.C. § 103

Claim 15 was rejected under 35 U.S.C. § 103(a) as being obvious over *Jacobson*, as applied to claims 13-14 and 16-26, in view of U.S. Patent No. 6,015,804 issued to Golub (“*Golub*”). Applicants respectfully submit that a *prima facie* case of obviousness has not been established because the cited references do not teach or suggest all of the limitations of claim 13. *Jacobson* does not teach or suggest all of the claim limitations of independent claim 13 for the reasons set forth in section II of this Response. *Golub* does not cure this lack of teaching or suggestion because the Examiner has not relied upon and Applicants cannot discern anywhere in *Golub* that teaches or suggests the elements that are not disclosed in *Jacobson*. Applicants further

incorporate by reference their previous arguments with respect to *Golub* in previous responses to office actions. Dependent claim 15 depends from independent claim 13 and therefore includes all of the limitations thereof. In view of the above remarks, Applicants respectfully submit that dependent claim 15 is allowable over the cited references.

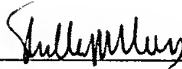
CONCLUSION

In view of the foregoing, it is believed that all claims now pending patentably define the subject invention over the prior art of record, and are in condition for allowance and such action is earnestly solicited at the earliest possible date. If the Examiner believes that a telephone conference would be useful in moving the application forward to allowance, the Examiner is encouraged to contact the undersigned at (310) 500-4787.

Respectfully submitted,

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CERTIFICATE OF TRANSMISSION

I hereby certify that this correspondence is being submitted electronically via EFS Web to the United States Patent and Trademark Office on August 28, 2007.



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